



Please type a plus sign (+) inside this box → ☒

Approved for use through 10/31/2001. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|---|------------------------|----|---|----------------------|-----------------------|
| Substitute for form 1449A/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | | | Application Number | 10/057,629 |
| | | | | Filing Date | January 25, 2002 |
| | | | | First Named Inventor | Harry R. Davis et al. |
| | | | | Group Art Unit | 1617 |
| | | | | Examiner Name | San Ming R. Hui |
| Attorney Docket Number | CV01382KUS/4686-045584 | | | | |
| Sheet | 1 | of | 1 | | |

| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS | | | |
|---|-----------------------|---|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cite and/or country where published. | T ² |
| SM | 1 | Nguyen LB, et al., "A molecular defect in hepatic cholesterol biosynthesis in sitosterolemia with xanthomatosis" J Clin Invest, 86: 923-931 (1990) | |
| | 2 | Lien B. Nguyen, et al., "Regulation of Cholesterol biosynthesis in sitosterolemia: effects of lovastatin, cholestyramine, and dietary sterol restriction" Journal of Lipid Research, Vol. 32, pp. 1941-1948 (1991) | |
| | 3 | T.A. Mietinen, "inhibition of cholesterol absorption by HMG-CoA reductase inhibitor" Eur J Clin Pharmacol (1991) 40 [Suppl 1]: S19-S 21 | |
| | 4 | H. Vanhanen, et al., "Pravastatin Lowers Serum Cholesterol, Cholesterol-Precursor Sterols, Fecal Steroids, and Cholesterol Absorption in Man", Metabolism, Vol. 47, No. 6 (June), (1992) pp. 588-595 | |
| | 5 | Matti I.J. Uusitupa, et al., "Lathosterol and Other Noncholesterol Sterols During Treatment of Hypercholesterolemia With Lovastatin Alone and With Cholestyramine or Guar Gum" Arteriosclerosis and Thrombosis, Vol. 12, No. 7, 807-813 (1992) | |
| | 6 | Zetia Product Brochure, Merck/Schering-Plough Pharmaceuticals (October 2002). | |
| SM | 7 | R. Steiner et al., "Sitosterolemia", http://www.emedicine.com/ped/topic_2110.htm (4/5/2005). | |
| | | | |
| | | | |
| | | | |

| | | | |
|--------------------|--------------------|-----------------|---------|
| Examiner Signature | <i>[Signature]</i> | Date Considered | 5/16/05 |
|--------------------|--------------------|-----------------|---------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Approved for use through 10/31/2001. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
This document contains information unless it contains a valid OMB control number.

Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | | | | | |
|--|---|----|---|------------------------|------------------------|
| Substitution for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | | | Complete If Known | |
| | | | | Application Number | 10/057,629 |
| | | | | Filing Date | January 25, 2002 |
| | | | | First Named Inventor | Harry R. Davis et al. |
| | | | | Group Art Unit | 1817 |
| | | | | Examiner Name | San Ming R. Hui |
| | | | | Attorney Docket Number | CV01382KUS/4686-045584 |
| Sheet | 1 | of | 1 | | |

[illegible]

| | | |
|--------------------|-----------------|---------|
| Examiner Signature | Date Considered | 5/16/05 |
|--------------------|-----------------|---------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication, if applicable.

⁴Unique citation designation number. ⁵See attached Kinds of U.S. Patent Documents. ⁶Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁷For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁸Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁹Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

PAGE 9/18 * RCVD AT 5/10/2005 3:20:09 PM [Eastern Daylight Time] * SVR:USPTO-EFXRF-1/1 * DNIS:8729306 * CSID: * DURATION (mm:ss):12:08